Complete Summary

GUIDELINE TITLE

Practice parameter: Steroids, acyclovir, and surgery for Bell´s palsy (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology.

BIBLIOGRAPHIC SOURCE(S)

Grogan PM, Gronseth GS. Practice parameter: Steroids, acyclovir, and surgery for Bell's palsy (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2001 Apr 10;56(7):830-6. [25 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Bell´s palsy

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Neurological Surgery
Neurology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To determine if steroids, acyclovir, and surgical facial nerve decompression are effective in improving facial functional outcomes in Bell´s palsy and to propose recommendations for the use of these therapies

TARGET POPULATION

Patients with Bell´s palsy

INTERVENTIONS AND PRACTICES CONSIDERED

1. Steroids such as, hydrocortisone, oral prednisone, or prednisolone
2. Acyclovir
3. Surgical facial nerve decompression

MAJOR OUTCOMES CONSIDERED

- Relative rate and 95% confidence interval for good recovery of facial function
- Relative rate and 95% confidence interval for complete recovery of facial function

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The authors searched the National Library of Medicine´s MEDLINE database from 1966 to June 2000. Three searches were performed in which the authors combined the term "facial paralysis or Bell´s palsy" with "prednisone or prednisolone or hydrocortisone", "acyclovir", and "surgery". The authors subsequently screened the resultant articles and their references for those studies that compared outcomes in prospectively assembled Bell´s palsy patients treated with steroids, acyclovir, or surgery to concurrent patients not treated with these modalities.

NUMBER OF SOURCE DOCUMENTS

Articles identified through searches

230 articles for steroid use

92 articles for acyclovir

104 articles for surgical facial nerve decompression

Subset of prospective outcome studies

9 articles for steroid use (see Table 1 in the original guideline document)

3 articles for acyclovir (see Table 2 in the original guideline document)

4 articles for surgical nerve decompression (see Table 3 in the original guideline document)

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Definitions for classification of evidence

Class I. Evidence provided by a randomized, controlled clinical trial with masked outcome assessment in a representative population. The following are required: a) primary outcomes are clearly defined; b) exclusion and inclusion criteria are clearly stated; c) adequate accounting of dropouts and crossovers with numbers sufficiently low to have minimal potential for bias; and d) relevant baseline characteristics are substantially equivalent among treatment groups.

Class II. Evidence provided by a prospective matched group cohort study in a representative population with masked outcome assessment that meets a through d above or a randomized, controlled clinical trial that lacks one criterion a through d.

Class III. All other controlled trials (including well-defined natural history controls or patients serving as their own controls) in a representative population where outcome assessment is independent of patient treatment.

Class IV. Evidence from studies not assessing outcomes independent of treatment, uncontrolled studies, case series, case reports, or expert opinion.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Summarized Patient Data
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

The following study design characteristics were extracted from the identified articles:

- Cohort size and study setting
- Treatment allocation method
- Age, sex, severity of palsy, and duration of palsy before treatment

- Medication regimen used or decompression procedure performed
- Length of follow-up
- Percentage of patients completing the study
- Method of facial function outcome assessment, including the use of masking

The authors graded the quality of the evidence provided by each study (class I, II, III, IV) using the classification-of-evidence scheme in the field "Rating Scheme for the Strength of the Evidence" and Appendix 1 of the original guideline document. In this scheme, class I studies are judged to have a low risk of bias and class IV studies are judged to have a high risk of bias. Studies were graded independently by each author. Differences were resolved after discussion.

Only studies receiving a grade of class III or better were considered in the formulation of the recommendations. The authors formulated practice recommendations after considering the estimated effect sizes, the significance of the effect, and the consistency of the effect between studies.

To account for the quality of the evidence, the authors determined a strength-of-recommendation level for each recommendation using the scheme in the National Guideline Clearinghouse (NGC) Guideline Summary "Major Recommendations" field and in Appendix 2 of the original guideline document.

Meta-Analytic Techniques - Pooled Relative Rates

For each study, using two-by-two tables, the authors compared the proportion of patients recovering good facial function in the treated group to the proportion of patients recovering good facial function in the control group by calculating the relative rate (RR) by means of the following formula:

Relative Risk = [A/(A+C)/[B/(B+D)]

Where A is the number of patients in the treated group having a good recovery; B is the number of patients in the control group, having a good recovery; C is the number of patients in the treated group having a poor recovery; and, D is the number of patients in the control group having a poor recovery.

In separate analyses, the authors calculated the relative rate at which patients in the treated group recovered complete facial function. They also calculated the 95% confidence interval of the relative rate.

In studies using the House and Brackmann facial function scoring system, the authors considered an outcome of grade I or II a good recovery. When comparing the proportion of patients recovering complete facial function, the authors considered an outcome of grade I a complete recovery. In studies using the Adour/Swanson grading scale, the authors considered a facial paralysis recovery profile of greater than seven and a recovery index of greater than five a good recovery. The authors considered a facial paralysis recovery profile of 10 and a facial paralysis recovery index of 10 a complete recovery.

When necessary to improve the precision of the measured relative risk, the authors pooled the results from different studies using general variance-based

meta-analytic techniques. To minimize the risk of bias in the resulting summary estimate of effect, the authors pooled studies with the lowest risk of bias first, adding studies with a higher risk of bias only when necessary to further increase precision.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Definitions for Strength of Recommendations:

Level A. Established as effective, ineffective, or harmful for the given condition in the specified population. Usually, an "A" recommendation requires that the pooled result from two or more distinct class I studies demonstrates a consistent, significant, and important effect.

Level B. Probably effective, ineffective, or harmful for the given condition in the specified population. Usually, a "B" recommendation requires that a single class I study demonstrates a significant and important effect or the pooled result from two or more distinct class II studies demonstrates a consistent, significant, and important effect.

Level C. Possibly effective, ineffective, or harmful for the given condition in the specified population. Usually, a "C" recommendation requires that a single class II study demonstrates a significant and important effect or the pooled result of two or more distinct class III studies demonstrates a consistent, significant, and important effect.

Level U. Data are inadequate or conflicting. Given current knowledge, treatment is unproven and an evidence-based recommendation cannot be made.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were approved by the American Academy of Neurology Quality Standards Subcommittee on July 29, 2000, by the Practice Committee on August 5, 2000, and by the American Academy of Neurology Board of Directors on October 7, 2000.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Excerpted by the National Guideline Clearinghouse (NGC):

Each clinical recommendation is rated based on the strength of the evidence. Definitions of the strength of the recommendations (Level A-C, Level U) and quality of the evidence (Class I-Class IV) are presented at the end of the Major Recommendations field.

Steroid-Use for the Treatment of Bell´s Palsy

Because of the absence of sufficiently powered class I studies, the authors conclude that a benefit of steroids in Bell´s palsy has not been definitively established. However, the available evidence supports a level "B" recommendation. Thus, based on the pooled result of class I and class II studies and a relatively benign side effect profile, the authors conclude that steroids are safe and probably effective in improving facial functional outcomes in patients with Bell´s palsy.

Acyclovir for the Treatment of Bell´s Palsy

Because of the absence of class I studies, the authors conclude that a benefit of acyclovir in Bell´s palsy has not been definitively established. However, the available evidence supports a level "C" recommendation. Thus, based on the result of a single class II study and a relatively benign side effect profile, the authors conclude that acyclovir (combined with prednisone) is safe and possibly effective in improving facial functional outcomes in patients with Bell´s palsy.

Facial Nerve Decompression Surgery for the Treatment of Bell´s Palsy

The risk of bias in all studies describing facial outcomes in surgically treated Bell´s palsy patients was too high to support evidence-based conclusions. Additionally, serious complications, including permanent hearing loss, were reported from surgical facial nerve decompression. For these reasons, the authors were unable to develop evidence-based recommendations for the use of facial nerve decompression in patients with Bell´s palsy.

Summary of Practice Recommendations

For patients presenting with Bell´s palsy:

- Early treatment with oral steroids is recommended as probably effective to improve facial functional outcomes (Level B).
- Early treatment with acyclovir in combination with prednisone is recommended as possibly effective to improve facial functional outcomes (Level C).
- There is insufficient evidence to make recommendations regarding the use of facial nerve decompression to improve facial functional outcomes (Level U).

Definitions:

Strength of Recommendations:

Level A. Established as effective, ineffective, or harmful for the given condition in the specified population. Usually, an "A" recommendation requires that the pooled result from two or more distinct class I studies demonstrates a consistent, significant, and important effect.

Level B. Probably effective, ineffective, or harmful for the given condition in the specified population. Usually, a "B" recommendation requires that a single class I study demonstrates a significant and important effect or the pooled result from two or more distinct class II studies demonstrates a consistent, significant, and important effect.

Level C. Possibly effective, ineffective, or harmful for the given condition in the specified population. Usually, a "C" recommendation requires that a single class II study demonstrates a significant and important effect or the pooled result of two or more distinct class III studies demonstrates a consistent, significant, and important effect.

Level U. Data are inadequate or conflicting. Given current knowledge, treatment is unproven and an evidence-based recommendation cannot be made.

Classification of Evidence:

Class I. Evidence provided by a randomized, controlled clinical trial with masked outcome assessment in a representative population. The following are required: a) primary outcomes are clearly defined; b) exclusion and inclusion criteria are clearly stated; c) adequate accounting of dropouts and crossovers with numbers sufficiently low to have minimal potential for bias; and d) relevant baseline characteristics are substantially equivalent among treatment groups.

Class II. Evidence provided by a prospective matched group cohort study in a representative population with masked outcome assessment that meets a through d above or a randomized, controlled clinical trial that lacks one criterion a through d.

Class III. All other controlled trials (including well-defined natural history controls or patients serving as their own controls) in a representative population where outcome assessment is independent of patient treatment.

Class IV. Evidence from studies not assessing outcomes independent of treatment, uncontrolled studies, case series, case reports, or expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

Only studies receiving a grade of class III or better were considered in the formulation of the recommendations.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

For patients with Bell´s palsy, a benefit from steroids, acyclovir, or facial nerve decompression has not been definitively established. However, available evidence suggests that steroids are probably effective and acyclovir (combined with prednisone) is possibly effective in improving facial functional outcomes.

POTENTIAL HARMS

- Side effects of steroids occurred in 1 to 4% of treated patients in three of the studies reviewed for this guideline. These side effects, in descending order of frequency, were dyspepsia, loss of blood sugar control, recurrent duodenal ulcers, mood swings, and acute psychosis. All effects resolved when treatment was stopped.
- The reported frequencies and nature of side effects in the acyclovir trials were similar to those with steroids. It was impossible to determine if the side effects reported were secondary to acyclovir or prednisone use.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The American Academy of Neurology recognizes that specific care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

The recommendations provided in this guideline are based on the best available evidence regarding the effectiveness of steroids, acyclovir, and facial nerve decompression for Bell's palsy. All of the studies reviewed had flaws, including insufficient statistical power and bias-prone methodologies that preclude definitive conclusions.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Grogan PM, Gronseth GS. Practice parameter: Steroids, acyclovir, and surgery for Bell's palsy (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2001 Apr 10;56(7):830-6. [25 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Apr

GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Neurology (AAN)

GUIDELINE COMMITTEE

Quality Standards Subcommittee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Gary Franklin, MD, MPH (Co-Chair); Catherine Zahn, MD (Co-Chair); Milton Alter, MD, PhD; Stephen Ashwal, MD; John Calverley, MD; Richard M. Dubinsky, MD; Jacqueline French, MD; Michael Glantz, MD; Gary Gronseth, MD; Deborah Hirtz, MD; Robert G. Miller, MD; James Stevens, MD; and William Weiner, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the AAN Web site.

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

AVAILABILITY OF COMPANION DOCUMENTS

- Practice statement definitions. St. Paul (MN): American Academy of Neurology.
- Practice statement development. St. Paul (MN): American Academy of Neurology.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 12, 2002. The information was verified by the guideline developer as of March 29, 2002.

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